

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/403,437 12/20/99 ODIDI

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HM12/0504

EXAMINER

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1900 CHEMED CENTER
CINCINNATI OH 45202

PULLIAM, A

ART UNIT	PAPER NUMBER
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1615

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DATE MAILED: 05/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/403,437	ODIDI ET AL.
	Examiner	Art Unit
	Amy E Pulliam	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 March 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-30 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the Amendment B, received March 22, 2001.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 3,870,790 to Lowey *et al.*, in view of US 5,162,117 to Stupak *et al.*. Lowey *et al.* teach a solid pharmaceutical composition in which the core comprises a pharmaceutical active, and a carrier made of hydroxypropylmethyl cellulose admixed with ethylcellulose (abstract). Lowey *et al.* teach that the formulation will release the active over a prolonged period of time. Lowey *et al.* also allow for the inclusion of various excipients. Lastly, Lowey *et al.* teach that their invention can be used with any active ingredient. They state, "the nature of the therapeutic agent is not critical and any drug, or stable combination of drugs, can be incorporated into these novel pharmaceutical forms." (see c 5, l 59-62). Lowey *et al.* does not teach the specific additives and excipient as claimed by applicant.

Stupak *et al.* is relied upon for the teaching that applicant's claimed excipients are all very well known in the pharmaceutical art, and therefore would have been obvious to include in any pharmaceutical formulation, especially one which has the same function of controlled release. Stupak *et al.* disclose a controlled release solid dosage tablet. More specifically, Stupak *et al.* teach that the tablet core of their invention can include excipients including diluents such as microcrystalline cellulose, lubricants, glidants such as silicon dioxide, as well as sodium lauryl sulfate and lactose (c 2-3). Additionally, Stupak *et al.* teach that their composition can have a coating, which can be a methacrylic acid copolymer coating (c 5, claim 5). Again, the Stupak reference is relied upon to show that applicant's claimed excipients are all known in the art of pharmaceutical formulations, and therefore would be obvious to include in a tablet formulation.

It is the position of the examiner that the main component of applicant's invention is the mixture of polymers in the core of the composition, which is disclosed generally by Lowey *et al.*. Lowey *et al.* does not teach that the hydrophilic polymer be a mixture of hydroxypropylmethylcellulose and hydroxyethylcellulose. However, it is the position of the examiner that because these two polymers act so similarly, and are often interchangeable in a pharmaceutical composition, it would have been obvious to one of ordinary skill in the art to use one or the other or a mixture of the two hydrophilic polymers. As stated in *In Re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), "It is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be

used for the very same purpose. As this court explained in Crockett, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their having been individually taught in the prior art. Therefore, because Lowey *et al.* teach the mixing of HPMC with ethylcellulose, it is the position of the examiner that Lowey *et al.*'s disclosure in view of Stupak's disclosure suggests applicant's claimed invention. Further, one of ordinary skill in the art would have been motivated to combine the teachings of Lowey *et al.* and Stupak *et al.*, and use any of the well known pharmaceutical excipients in the composition disclosed by Lowey *et al.*. The expected result would be a successful controlled release pharmaceutical composition. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments filed March 22, 2001 have been fully considered but are not found persuasive. Applicant has amended the claim to specify particular polymers for the second polymer component. More specifically, applicant has limited the second polymer component to hydroxyethyl cellulose or hydroxypropylmethyl cellulose and hydroxyethyl cellulose. Applicant argues that Lowey does not teach this specific limitation. It is the position of the examiner that Lowey in view of Stupak still obviates the claimed invention for the following reasons. First, Lowey teaches a mixture of polymer components, wherein the polymers have opposite wettability characteristics. (Ethylcellulose is hydrophobic and HPMC is hydrophilic). Second, as stated in the above rejection, it is the position of the examiner that hydroxyethyl cellulose and

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hydrocyclopoly(methyl cellulose) have such similar properties that they are known in the art to be used interchangeably. As Lowey teaches HPMC, it is the position of the examiner that one of ordinary skill in the art would have been motivated to either substitute the similar polymer HEC for HPMC, or to combine the two. Again, the examiner relies upon *In Re Kerkhoven*, which states that it is obvious to combine two compositions which are useful for the same purpose to form a third composition useful for that same purpose. Third, on page 5, lines 7 and 8 of applicant's specification, applicant teaches that polymers which can be used as the second polymer component of their invention can be HEC and/ or HPMC. This teaching reiterates the examiner's position the HEC and HPMC are interchangeable.

Applicant further argues that Lowey teaches a controlled release formulation which will only release for between 1 and 8 hours. However, column 2, lines 31-36 of Lowey clearly states that the release time, the dosage unit and the pattern of release can be controlled by the relative amounts of the HPMC and EC employed. Furthermore, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., release over 24 hours) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Additionally, applicant has added new claims 30, which includes a moisture content of the composition which is less than 3%. Applicant argues that Lowey teach a

moisture content as high as 25%. However, the examiner would like to point out that Lowey also teaches a moisture content as low as 5% (abstract). The examiner finds no critical difference between 3% and 5%, absent a showing of criticality.

Lastly, in response to applicant's arguments against the Stupak reference individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Therefore, the above rejection is maintained and applied to new claim 30.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Amy E. Pulliam
Patent Examiner
Art Unit 1615
May 2, 2001


THURMAN K. PAGE
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